

### REMARKS AND ARGUMENTS

Claims 1-3, 5-26, and 32-61 are pending in the application. Claims 4 and 27-31 were previously withdrawn, without prejudice. To simplify and facilitate the Examination, Applicants cancel claims 17-21 and 53-56, without prejudice, and with the intent of resubmitting those claims in a subsequently filed continuation patent application. The following Remarks and Arguments focus on the remaining independent claims of the application, *i.e.*, claims 1, 22, 32, 36, 52, and 58, and more particularly, to certain novel elements common to these claims.

Applicants and Applicants' representative wish to thank the Examiner for his availability for a telephone consultation on April 22, 2003 concerning the outstanding Office Action. Applicants believe that the consultation and the Examiner's direction and comments will facilitate the prosecution of the present case.

Claims 1-3, 5, 9-14, 17-20, and 22-26 are rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA Irritant Smoke Protocol (the "OSHA reference"), in view of U.S. Patent No. 3,834,241 (Garren '241). Claims 6 and 7 are rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of U.S. Patent 3,834,241 (Garren '241), and further in view of U.S. Patent No. 5,073,347 (Garren '347). Claim 15 is rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of Garren '241, and further in view of U.S. Patent No. 3,938,392 (Rodrigues '392).

Claims 8, 16, 21, 32-46, and 52-57 are rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of Garren '241 and further in view of U.S. Patent No. 3,840,009 (Michaels '009). Claims 36, 48, 49, 51, 58, 60, and 61 are rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of Garren '241 and further in view of U.S. Patent No. 5,302,344 (Perlman '344). Claims 50 and 59 are rejected under 35 U.S.C. 103(a), as being unpatentable over the OSHA reference in view of Garren '241 and Perlman '344, and further in view of U.S. Patent No. 6,098,802 (Asa '802). Finally, claim 47 is rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of Garren '241 and Michaels '009 and further in view of Rodrigues '392.

Applicants respectfully traverse each of the above 35 U.S.C. § 103(a) rejections. It is applicant position that the combination of the OSHA reference and the Garren '241 reference does not render any of the independent claims obvious.

Amended Claim 1 recites an apparatus for testing equipment located in a local environment by presenting a detectable indicator gas therein. The apparatus includes a one-piece, polymeric pump and container portion combination, a chemical substance stored in the container portion and which is reactive with the local environment, wherein the polymeric pump is integrally formed as one piece with the container portion and joined seamlessly with the container portion, and an outlet that is severable to direct indicator gas into the local environment. Further, Claim 1 is amended to recite, and highlight, that the pump and the container portion are in fluid communication and define an internal environment that includes the chemical substance and is sealed from the local environment.

Although the OSHA reference discloses a testing apparatus, it does not teach an apparatus that has a polymeric pump portion that is (1) integrally formed as one piece with the container portion, (2) joined seamlessly with the container portion, and (3) wherein the one-piece, polymeric pump and container portion are in fluid communication and define an internal environment that includes a chemical substance reactive with the local environment and is sealed from the local environment. The OSHA reference calls, instead, for the use of a specific size pump that is separate from the smoke tube. Garren '241 is cited in the Office Action as cure to the deficiencies of the OSHA reference. Specifically, Garren '241 is cited as disclosing the use of a plastic pump integrated with a plastic pipette and thus, as teaching or suggesting a substitute of the separate pump and glass tube combination in the OSHA reference.

The Examiner has the initial burden of presenting a *prima facie* case of obviousness. M.P.E.P. § 2142-43; see also *In re Peeks*, 612 F.2d 1287 (CCPA 1980). This requires the Examiner to meet three basic criteria. If the Examiner fails to meet any one of these three basic criteria, he has failed to present a *prima facie* case and any rejection based on 35 U.S.C. § 103(a) is improper. Applicants believe that, in the present case, one or more of the these three basic criteria has not been met. Accordingly, the standing rejections under 35 U.S.C. § 103(a) are improper.

(1) *All claim limitations are not taught or suggested by any combination of the cited references.*

A first criteria requires the Examiner to establish that all claim limitations are taught or suggested by the prior art. *In Re Roy*, 490 F.2d 981 (C.C.P.A. 1974). Applicants point out that none of Garren '241, the OSHA reference, and the combination of the two, teaches or suggests a one-piece polymeric structure (and more particularly, a polymeric pump and container portion combination) having two portions that are in fluid communication, define an internal environment that is sealed from the local environment, and stores a chemical substance reactive with the local environment (which limitations are recited in amended claim 1). Although the Garren '241 reference teaches the construction of a polymeric pipette portion, the pipette portion cannot be sealed as required by the present invention (without defeating the dispensing purpose of the pipette).

(2) *The suggested combination of cited references does not provide any teaching, incentive, or suggestion to combine these references.*

In any event, a combination of prior art teachings, such as the OSHA reference and Garren '241, cannot be shown to establish obviousness absent some teaching, incentive, or suggestion in these references. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 (Fed. Cir. 1984); *In Re Fine*, 837 F.2d 1071 (C.A.F.C. 1988). This a second basic criteria required of *prima facie* obviousness. M.P.E.P. § 2142-43. In the present case, no indication is made as to where in any of the cited references the requisite teaching, incentive, or suggestion may be found. For this reason as well, the combination of references suggested by the Examiner does not provide a proper basis for a rejection under 35 U.S.C. § 103(a).

The application of an integrally formed, seamlessly joined combination in the pipette art does not necessarily, readily apply to the smoke tube art. Applicants believe that the smoke tube art is a unique, unsophisticated but mature art, wherein change and innovation is uncommon. The primary concern in the manufacture of the smoke tube has been low cost and guaranteed performance. These concerns have traditionally been addressed by the low-cost, two-piece squeeze pump-glass tube design, and no motivation or incentive has surfaced to modify or deviate from this simple but effective design.

Furthermore, no one has even contemplated the use of an integrally formed tube-and-pump apparatus because of the different properties that each component required. The pump or squeeze bulb must be formed from a flexible material that can be squeezed, while the tube portion must be formed from a material that is sufficiently impermeable so as to protect the chemical in the container portion from reacting with the local environment until the test is ready to be performed. These two necessary properties, flexibility and impermeability, are not usually found in one material, and so the general perception in the art taught away from the present invention. That is, the general perception taught that two separate components must be used – a pump and a container – and attached just prior to performing the test.

This perception (or mis-perception) was further supported by the availability of low cost, glass container portions. In fact, the glass smoke tube has been the only design for several decades. Applicants agree that integrally forming and joining seamlessly two components are not novel, and that, in fact, such a manufacturing technique has been known throughout the several decades that glass smoke tubes have been around. The fact that such a manufacturing variation has been available, however, further supports the argument that the application of that combination to the smoke tube art is non-obvious. A primary reason for this has been the perceived adequacy of the glass smoke tube. Another reason is a reluctance by manufacturers to risk trying a new design to address important health and safety issues: 1) to prevent leakage of potentially harmful chemical substances like stannic chloride, and 2) to ensure the effectiveness of a safety device, such as a smoke tube, by preventing contamination of the reactive substance prior to test. Such a risk has potential for legal and financial liabilities.

Moreover, Applicants submit that the pipette art is associated with laboratory type equipment and is not necessarily related to the smoke tube/field equipment art. One difference is that the smoke tube art is generally an unsophisticated art primarily concerned with minimizing cost and risk. Also, the two arts define two separate marketplaces and class of users. Thus, those designers or users concerned with the smoke tube art, if motivated to address a problem or deviate from the glass tube solution, will not look to or necessarily happen upon, the teachings of the pipette art.

3) *The suggested combination of references do not show any reasonable expectation of success from the combination.*

To satisfy a third basic criteria of *prima facie* obviousness, one must show a reasonable expectation of success from the combination of the OSHA reference and Garren '241 or the modification of the OSHA reference to incorporate the teachings of Garren '241. Again, the cited references do not teach or suggest the proposed combination or modification. Thus, no reasonable expectation of success (or synergy resulting from the combination) can be found. Applicants further note that the requisite motivation or desirability of a combination cannot be derived from benefits resulting from the claimed combination when only the patent discloses those benefits or any reasonable expectation of success, as is the case here.

Even if all elements of claim 1 were available from the cited references, there is no teaching in the cited references, or from the general knowledge available to one of ordinary skill in the art, which would allow the teachings of these two references to be combined so as to produce a workable product according to the claimed invention. The polymeric pump and tube combination suggested by the Garren '241 reference would not preserve the chemical substance and would not control generation of the indicator gas. Specifically, the container portion would not provide the proper seal in the presence of an open pipette end and is susceptible to moisture contamination due to the permeability of the plastic pump and tube. These, in fact, are a problem and concern that discouraged manufacturers and users from employing anything but enclosed glass tubes and separate pumps.

Accordingly, the combination of the Garren '241 reference and the OSHA reference does not provide a proper basis for a rejection under 35 U.S.C. § 103(a). Withdrawal of the Examiner's rejection of independent claims 1 and 22, and claims dependent from these claims under 35 U.S.C. § 103(a) is respectfully requested.

With respect to independent claims 32 and 52, Applicants submit that neither the Perlman '344 reference nor the ASA '802 portion teaches or suggests a laminate that substantially encases the pump-container portion structure, as required by the amended claims. Example 4 of Perlman '344 refers only to prepackaging that is removed prior to an autoclaving process. Applicants also note that Perlman '344 is directed to laboratory equipment, which is not the relevant art, and not field instrumentation. As for the ASA '802 reference, the film disclosed therein is used only to cover a portion of the prepackaging and thus, does not completely encase the apparatus at any point.

Accordingly independent claims 32 and 52, claims dependent from these claims, are also patentable over the cited references.

Attached hereto is a version of the pending claims marked up, captioned **“Version With Markings To Show Changes Made.”** Also attached is a clean version of the claims pending in the application, after the current amendment, captioned **“Clean Version of Pending Claims.”**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If the appropriate Petition for an Extension of Time is not attached hereto (or any other Petition required of the application), this statement shall serve as Applicants’ Petition to the U.S.P.T.O. Please charge any fees that are due for any Petition or any fee required of this filing to the deposit account of Fulbright & Jaworski L.L.P., Account No. 06-2375 under Order No. P02054US1 (10024546).

The undersigned is available for consultation at any time, if the Examiner believes such consultation may expedite the resolution of any issues.

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Respectfully submitted,

By 

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**Version With Markings to Show Changes Made****In the Claims**

1. An apparatus for testing equipment located in a local environment by presenting a detectable indicator gas therein, said apparatus comprising:

a one-piece, polymeric pump and container portion combination;

a chemical substance stored in said container portion, said substance being reactive with the local environment;

[a] wherein said pump is operable to draw air into said container portion and in contact with said chemical substance to generate a detectable indicator gas, wherein said pump is integrally formed as one piece, and [wherein said pump is] joined seamlessly, with said container portion such that said pump and said container portion are in fluid communication and define an internal environment that includes said chemical substance and is sealed from the local environment; and

an outlet to said container [for] that is severable to direct[ing] said indicator gas into the local environment.

8. The testing apparatus of claim 1, wherein said container portion and said pump are formed from a laminate of at least a first material layer and a second material layer distinct from said first material layer, said first material layer having a polymeric material and said second layer being a material layer that is substantially more impermeable than said polymeric layer,

wherein said second material layer completely encases said first material layer, said container portion, and said pump.

22. A method of testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

storing a chemical substance, reactive with air to produce an indicator gas, in a container formed substantially from a polymeric material;

providing a polymeric squeeze bulb device in operative communication with the container, and formed integrally, as one piece, and seamlessly joined, therewith, such that the squeeze bulb device and the container are in fluid communication and define an internal environment that is sealed from the local environment;

breaking a portion of the container tube to provide an outlet;

operating the squeeze bulb to draw air past the chemical substance to produce a human detectable indicator gas;

directing the indicator gas outward of the container and into the local environment;  
and

detecting the indicator to determine the operability of the equipment in the local environment.

32. A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a flexible material;

providing a second material;

integrally forming, as one piece, a container portion and a squeeze bulb portion using the flexible material and applying the second material adjacent the flexible material to form a laminate therewith such that the laminate is substantially less permeable than the flexible material; and

storing a chemical substance in the container portion such that upon operation of the bulb to draw air into the container portion, a detectable indicator gas is generated for presentation into the local environment, whereby the container portion and the pump are in fluid communication and define an internal environment that includes a chemical substance and is sealed from the local environment.

36. An apparatus for testing equipment located in a local environment by



presenting a detectable indicator gas therein, said apparatus comprising:

a one-piece polymeric pump and container portion combination defining a sealed internal environment;

a chemical substance stored in said container portion[;] ,

[a] wherein said pump is operable to draw air into said container and in contact with said chemical substance to generate a detectable indicator gas; and

[an] a severable outlet to said container for directing said indicator gas into the local environment;

wherein said container portion and said pump are formed from a laminate of at least a first material layer and a second material layer distinct from said first material layer.

52. A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a first material having one or more physically advantageous properties;

providing a second material distinct from said first material and the second material having one or more physically advantageous properties;

integrally forming, as one piece, a container portion and a pump portion using the first material and applying the second material adjacent the first material and completely encasing the first material, container portion, and pump portion to form a laminate therewith such that the apparatus is characterized by the physically advantageous properties of the first material and the second material; and

storing a chemical substance in the container portion such that, upon operation of the bulb to draw air into the container portion, a detectable indicator gas is generated for presentation into the local environment[.];

wherein the first material is a polymeric material;

wherein said step of providing a first material includes selecting one or more physically advantageous properties selected from the group of physically advantageous properties including: flexibility, durability, high strength, tear resistance, and combinations thereof;

wherein said step of providing a second material includes selecting one or more physically advantageous properties selected from the group of physically advantageous properties including: low permeability, inertness, non-reactive with the chemical substance, and combinations thereof; and

wherein said step of storing includes storing a chemical that, when contacted by air drawn into the container portion, generates a visually detectable indicator gas.

Please cancel claims 53-56, without prejudice.

58. A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a testing device including the steps of:

providing a container portion,

storing a chemical substance in said container portion, and

using a polymeric material, integrally forming a squeeze bulb as one-piece with the container portion, such that the squeeze bulb is operable to draw air into the container portion to generate a reaction between the chemical substance and the air, and to produce a detectable indicator gas; and

surrounding the testing device with a packaging layer, the packaging layer being substantially liquid and gas impermeable than the polymeric layer.

**Version With Currently Pending Claims**

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1. An apparatus for testing equipment located in a local environment by presenting a detectable indicator gas therein, said apparatus comprising:

a one-piece, polymeric pump and container portion combination;

a chemical substance stored in said container portion, said substance being reactive with the local environment;

wherein said pump is operable to draw air into said container portion and in contact with said chemical substance to generate a detectable indicator gas, wherein said pump is integrally formed as one piece, and joined seamlessly, with said container portion such that said pump and said container portion are in fluid communication and define an internal environment that includes said chemical substance and is sealed from the local environment; and

an outlet to said container that is severable to direct said indicator gas into the local environment.

2. The testing apparatus of claim 1, wherein said pump is a manually squeezable bulb.

3. The testing apparatus of claim 1, wherein said pump is selected from the group of manually operable pumps consisting of: a manually squeezable bulb, a bellows-driven pump, a syringe, and combinations thereof.

5. The testing apparatus of claim 1, wherein said container portion and said pump are formed from a plastic material.

6. The testing apparatus of claim 5, wherein said plastic material is low density polyethylene.

7. The testing apparatus of claim 1, wherein said container portion is formed from a first material and said pump is formed from a second material distinct from said first material.

8. The testing apparatus of claim 1, wherein said container portion and said pump are formed from a laminate of at least a first material layer and a second material layer distinct from said first material layer, said first material layer having a polymeric material and said second layer being a material layer that is substantially more impermeable than said polymeric layer,

wherein said second material layer completely encases said first material layer, said container portion, and said pump.

9. The testing apparatus of claim 1, wherein said container portion and said pump form a substantially permanent molded structure.

10. The testing apparatus of claim 1, wherein said chemical substance is reactive with the container environment, upon operation of the pump, to generate said indicator gas.

11. The testing apparatus of claim 1, wherein said chemical substance is selected such that said chemical substance and air drawn into said container portion generate a scented indicator gas upon contact.

12. The testing apparatus of claim 1, wherein said chemical substance is reactive with air to produce an irritant gas.

13. The testing apparatus of claim 12, wherein said chemical substance is liquid  $\text{SnCl}_4$  and said indicator gas is an acid vapor fume.

14. The testing apparatus of claim 1, wherein said chemical substance is reactive with the container environment, upon operation of the pump, to generate a visually detectable indicator gas.

15. The testing apparatus of claim 1, wherein said pump has a hole to allow finger release of pressure.

16. The testing apparatus of claim 1, further comprising an exterior layer of laminate that seals the container.

22. A method of testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

storing a chemical substance, reactive with air to produce an indicator gas, in a container formed substantially from a polymeric material;

providing a polymeric squeeze bulb device in operative communication with the container, and formed integrally, as one piece, and seamlessly joined, therewith, such that the squeeze bulb device and the container are in fluid communication and define an internal environment that is sealed from the local environment;

breaking a portion of the container tube to provide an outlet;

operating the squeeze bulb to draw air past the chemical substance to produce a human detectable indicator gas;

directing the indicator gas outward of the container and into the local environment;  
and

detecting the indicator to determine the operability of the equipment in the local environment.

23. The method of claim 22, wherein the indicator gas is a visually observable gas, said detecting step including visually observing the behavior of the indicator gas in the local environment.

24. The method of claim 23, wherein said observing step includes visually observing the flow of the indicator gas in the local environment.

25. The method of claim 22, wherein the chemical substance is liquid  $\text{SnCl}_4$  or  $\text{H}_2\text{SO}_4$  and said step of operating the squeeze bulb generates a chemical reaction producing an irritant indicator gas.

26. The method of claim 22, wherein the indicator gas is indicator gas having a pre-selected scent, said observing step including detecting the scent of the indicator gas to determine the operability of the equipment.

32. A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a flexible material;

providing a second material;

integrally forming, as one piece, a container portion and a squeeze bulb portion using the flexible material and applying the second material adjacent the flexible material to form a laminate therewith such that the laminate is substantially less permeable than the flexible material; and

storing a chemical substance in the container portion such that upon operation of the bulb to draw air into the container portion, a detectable indicator gas is generated for presentation into the local environment, whereby the container portion and the pump are in fluid communication and define an internal environment that includes a chemical substance and is sealed from the local environment.

33. The method of claim 32, wherein said step of providing a flexible material includes providing a plastic material.

34. The method of claim 32, further comprising the step of sealing a breakable end tip of the container tube portion located opposite the squeeze bulb.

35. The method of claim 32, wherein the step of storing includes storing a chemical that, when contacted by air drawn into the container portion, generates a visually detectable indicator gas.

36. An apparatus for testing equipment located in a local environment by presenting a detectable indicator gas therein, said apparatus comprising:

a one-piece polymeric pump and container portion combination defining a sealed internal environment;

a chemical substance stored in said container portion,

wherein said pump is operable to draw air into said container and in contact with said chemical substance to generate a detectable indicator gas; and

a severable outlet to said container for directing said indicator gas into the local environment;

wherein said container portion and said pump are formed from a laminate of at least a first material layer and a second material layer distinct from said first material layer.

37. The apparatus of claim 36, wherein said pump is a manually squeezable bulb.

38. The apparatus of claim 36, wherein said pump is selected from the group of manually operable pumps consisting of: a manually squeezable bulb, a bellows-driven pump, a syringe, and combinations thereof.

39. The apparatus of claim 36, wherein said pump is joined seamlessly with said container portion.

40. The apparatus of claim 36, wherein said container portion and said pump are formed from a plastic material.

41. The apparatus of claim 40, wherein said plastic material is low density polyethylene.

42. The apparatus of claim 36, wherein said container portion and said pump form a substantially permanent molded structure.

43. The apparatus of claim 36, wherein said chemical substance is reactive with the container environment, upon operation of the pump, to generate said indicator gas.

44. The apparatus of claim 36, wherein said chemical substance is selected such that said chemical substance and air drawn into said container portion generate a scented indicator gas upon contact.

45. The apparatus of claim 44, wherein said chemical substance is liquid  $\text{SnCl}_4$  and said indicator gas is an acid vapor fume.

46. The apparatus of claim 36, wherein said chemical substance is reactive with the container environment, upon operation of the pump, to generate a visually detectable indicator gas.

47. The apparatus of claim 36, wherein said pump has a hole to allow finger release of pressure.

48. The apparatus of claim 36, wherein said second material layer seals said container.

49. The apparatus of claim 36, wherein said second material layer completely surrounds said testing apparatus.

50. The apparatus of claim 49, wherein said second material layer is a mylar bag.

51. The apparatus of claim 36, wherein said second material layer is sealably disposed about said pump and said container portion.

52. A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a first material having one or more physically advantageous properties;

providing a second material distinct from said first material and the second material having one or more physically advantageous properties;

integrally forming, as one piece, a container portion and a pump portion using the first material and applying the second material adjacent the first material and completely encasing the first material, container portion, and pump portion to form a laminate therewith such that the apparatus is characterized by the physically advantageous properties of the first material and the second material; and



storing a chemical substance in the container portion such that, upon operation of the bulb to draw air into the container portion, a detectable indicator gas is generated for presentation into the local environment;

wherein the first material is a polymeric material;

wherein said step of providing a first material includes selecting one or more physically advantageous properties selected from the group of physically advantageous properties including: flexibility, durability, high strength, tear resistance, and combinations thereof;

wherein said step of providing a second material includes selecting one or more physically advantageous properties selected from the group of physically advantageous properties including: low permeability, inertness, non-reactive with the chemical substance, and combinations thereof; and

wherein said step of storing includes storing a chemical that, when contacted by air drawn into the container portion, generates a visually detectable indicator gas.

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57. The method of claim 52, wherein said step of providing a second material includes providing a mylar material.

58. A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a testing device including the steps of:

providing a container portion,

storing a chemical substance in said container portion, and

using a polymeric material, integrally forming a squeeze bulb as one-piece with the container portion, such that the squeeze bulb is operable to draw air into the container portion to generate a reaction between the chemical substance and the air, and to produce a detectable indicator gas; and

surrounding the testing device with a packaging layer, the packaging layer being substantially liquid and gas impermeable than the polymeric layer.

59. The method of claim 58, wherein the packaging layer is a mylar material.

60. The method of claim 58, wherein the polymeric material is low density polyethylene.

61. The method of claim 60, wherein the packaging layer is substantially less permeable than the polymeric material, such that the step of surrounding the testing device substantially reduces the permeability of the testing device.

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